(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 September 2003 (12.09.2003)

PCT

(10) International Publication Number
WO 03/073960 A1

(51) International Patent Classification[7]: A61F 2/00

(21) International Application Number: PCT/IB03/01231

(22) International Filing Date: 28 February 2003 (28.02.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/361,503 1 March 2002 (01.03.2002) US

(71) Applicant and
(72) Inventor: **JACQUETIN, Bernard** [FR/FR]; 20 rue Valentin Vigneron, F-63100 Clermont-Ferrand (FR).

(74) Agent: **BOLLHALDER, Renato**; A. Braun Braun Héritier Eschmann AG, Holbeinstrasse 36-38, CH-4051 Basel (CH).

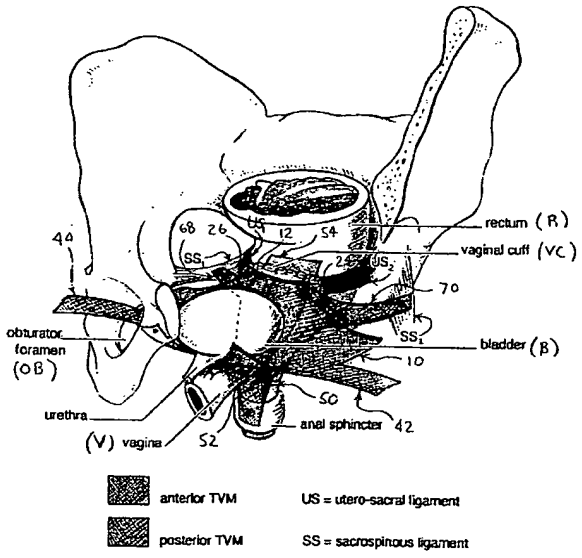
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR TREATING PELVIC ORGAN PROLAPSES IN FEMALE PATIENTS



(57) Abstract: An anterior implant (10) adapted to treat central and lateral cystoceles present in a female patient includes laterally extending stabilizing straps (42, 44) for supporting the implant between the patient's bladder and vagina independently of the patient's arcus tendineous fascia pelvis. Rectocele and hysterocele repairs can be carried out using a single posterior implant (50) which, like the anterior implant, is provided with laterally extending stabilizing straps (68, 70) for supporting the implant between the patient's rectum and vagina.

WO 03/073960 A1

METHOD AND APPARATUS FOR TREATING PELVIC ORGAN PROLAPSES IN FEMALE PATIENTS

Technical Field of the Invention

The present invention relates to surgical devices and procedures useful for treating pelvic organ prolapses in female patients.

Background Art

Women, often due to age, can experience three basic types of pelvic organ prolapses. These prolapses or defects are as follows: cystocele; hysterocele; and rectocele.

A cystocele occurs when the bladder bulges into the vagina. If the defect is confined to a centralized region, it is commonly referred to as a central cystocele. If the defect extends laterally beyond any such centralized region, the laterally extending portion(s) is commonly referred to as a lateral cystocele(s). Cystoceles, in general, are treated by an anterior repair which, in the past, has involved a suturing procedure or the use of an implant adapted to support the bladder in a hammock-like fashion (see, for instance, U.S. Patent No. 5,840,011 and WIPO Publication No. WO 02/38079 A2). The known suturing procedures suffer from a high re-occurrence rate. The aforementioned implants, while having proved successful for the treatment of a central cystocele, are not inherently designed to treat a lateral cystocele(s).

A rectocele occurs when the rectum bulges into the vagina. This type of defect is treated by a posterior repair which, in the past, has involved suspension of the vaginal apex to the cardinal and uterosacral ligaments. Variations of these procedures have been performed using various mesh materials.

A hysterocele occurs when the uterus descends into the vagina, resulting in a vaginal vault descent. The common treatment for such a defect is a hysterectomy, followed with a vaginal vault suspension carried out by, for instance, attaching the resulting vaginal cuff to the levator ani, to the cocuygenous muscle, or to one of the sacrospinous ligaments, but not to both of them (the Richter technique).

Disclosure of the Invention

One aspect of the present invention involves a new and improved anterior implant and a procedure for using it to make cystocele repairs in a female patient. More particularly, the anterior implant includes an inboard area adapted to treat a lateral cystocele and a pair of flanking outboard areas, each of which is adapted to treat a lateral cystocele. After positioning the body of the anterior implant between the patient's bladder and vagina, laterally extending straps are passed through the patient's obturator foramens and corresponding skin incisions in the patient's perineum. The straps function to stabilize the anterior implant on both sides thereof independently of the patient's arcus tendineous fascia pelvis. In one

embodiment, the anterior implant is provided with a pair of stabilizing straps, one on each side of the implant. In another embodiment, two pairs of stabilizing straps are provided, one pair extending laterally from one side of the anterior implant and another pair extending laterally from the opposite side of the anterior implant.

Another aspect of the present invention involves a new and improved posterior implant and a procedure for using it to treat a rectocele and/or a hysterocele present in a female patient. The posterior implant includes laterally extending straps for supporting the body of the posterior implant between the rectum and the vagina, while also functioning to perform a vaginal vault suspension through their attachment to the sacrospinous ligaments.

Brief Description of the Drawings

For a better understanding of the present invention, reference is made to the following detailed description of various exemplary embodiments considered in conjunction with the accompanying drawings, in which:

Fig. 1 is a top plan view of one exemplary embodiment of an anterior implant constructed in accordance with the present invention;

Fig. 2 is a top plan view of one exemplary embodiment of a posterior implant constructed in accordance with the present invention;

Fig. 3 is an illustration of a female's pelvic anatomy which has undergone surgical procedures using the implants of Figs. 1 and 2;

Figs. 4 and 5 illustrate two stages of a trans-obturator passage which is being performed as part of the surgical procedures depicted in Fig. 3;

Fig. 6 shows the implants of Figs. 1 and 2 as they are being implanted in a female patient;

Fig. 7 shows the anterior implant of Fig. 1 in place between a female patient's bladder and vagina;

Figs. 8 and 9 show the posterior implant of Fig. 2 in place between a female patient's rectum and vagina;

Fig. 10 is a top plan view of another exemplary embodiment of an anterior implant constructed in accordance with the present invention; and

Fig. 11 is a top plan view of another exemplary embodiment of a posterior implant constructed in accordance with the present invention.

Best Mode for Carrying Out the Invention

With reference to Fig. 1, an anterior implant 10 includes a lower portion 12 and an upper portion 14. While two distinct portions have been identified, it should be understood that the anterior implant 10 is preferably made from a single sheet of any suitable bio-compatible mesh material, such as a knitted polypropylene fabric (e.g., soft PROLENE® mesh marketed by Ethicon, Inc. of Somerville, New Jersey, U.S.A.). Accordingly, the imaginary

boundaries of the various portions are indicated in Fig. 1 by dotted lines (i.e., in phantom) to facilitate consideration and discussion of the anterior implant 10.

Returning now to Fig. 1, the lower portion 12, which has a generally funnel-like shape, is demarcated by a straight lower edge 16 having a length in a range of from about 2 cm to about 5 cm, an imaginary border 18 (indicated in phantom in Fig. 1) having a length in a range of from about 8 cm to about 14 cm, and a pair of concave side edges 20, 22 having a complex (i.e., compound) arcuate shape approximating that of a female patient's pelvic anatomy. Corners 24, 26 are formed where the lower edge 16 merges with the concave side edges 20, 22, respectively. It should be noted that the lower edge 16 can be extended by as much as about 3 cm (as indicated in phantom in Fig. 1) for a purpose to be described hereinafter.

The distance D_1 between the lower edge 16 and the imaginary border 18 is also selected as a function of the pelvic anatomy of the patient, but typically falls within a range of from about 4 cm to about 8 cm. Of course, the nature of the mesh fabric from which the anterior implant 10 is made is such that the surgeon can modify the size and shape of the lower portion 12 to meet the needs of a particular patient. In other words, the lower portion 12 of the anterior implant 10 can be custom fitted in the surgical arena.

Still referring to Fig. 1, the upper portion 14, which has a generally dome-like shape, is demarcated by the imaginary border 18 with the lower portion 12, a curved upper edge 28 having a radius (e.g., from about 2

cm to about 4 cm) and arcuate length (e.g., from about 2 cm to about 4 cm) selected so as to avoid contact with the bladder neck of the patient, and a pair of convex side edges 30, 32 having a complex arcuate shape approximating that of the arcus tendineous fascia pelvic (ATFP). The convex side edges 30, 32 of the upper portion 14 merge with the concave side edges 20, 22, respectively, of the lower portion 12 to form corners 34, 36, respectively, while corners 38, 40 are formed where the upper edge 28 merges with the convex side edges 30, 32, respectively.

The distance D_2, as measured along the central longitudinal axis (L) of the anterior implant 10 and between the imaginary border 18 and the upper edge 28, is selected as a function of the pelvic anatomy of the patient. Typically, the distance D_2 falls within a range of from about 3 cm to about 5 cm. Like the lower portion 12, the upper portion 14 is adapted for custom fitting in the surgical arena to meet the particular needs of a patient. Thus, it should be understood that the shape and size of the upper portion 14 are subject to post-manufacture modification by the surgeon during the course of a surgical procedure.

With continuing reference to Fig. 1, straps 42, 44 extend outwardly from opposite sides of the upper portion 14. More particularly, the strap 42 extends laterally outward from the convex side edge 30 of the upper portion 14, while the strap 44 extends laterally outward from the convex side edge 32 of the upper portion 14. The straps 42, 44, whose function will be described in detail hereinafter, typically have a width in a range of from about

.5 cm to about 2 cm, and a length in a range of from about 7 cm to about 15 cm. While the straps 42, 44 preferably have a slight curvature as shown in Fig. 1, they could also extend in a linear fashion from the convex sides edges 30, 32, respectively, of the anterior implant 10. As explained previously, the surgeon can readily modify the width and length of the straps 42, 44 by, for instance, cutting them with scissors or other suitable cutting instruments.

Imaginary boundary lines 46, 48, which extend generally parallel to the central longitudinal axis (L), divide the body of the anterior implant 10 into an inboard area A_1 and two outboard areas A_2, A_3 which flank the inboard area A_1. The areas A_1, A_2, and A_3 are not precise. Generally speaking, the area A_1 designates that portion of the anterior implant 10 which would function to repair a central or medial cystocele in accordance with a surgical procedure to be described in detail hereinafter, while the areas A_2, A_3 designate those portions of the anterior implant 10 which would function to repair lateral cystoceles in accordance with the same procedure.

With reference now to Fig. 2, a posterior implant 50 includes a lower portion 52, an upper portion 54, and a tape portion 56. Like the anterior implant 10, the posterior implant 50 is made from a single sheet of any suitable bio-compatible mesh material. Although the posterior implant 50 is depicted in Fig. 2 as being separate and distinct from the anterior implant 10, it should be understood that the posterior implant 50 can be formed integrally with the anterior implant 10 as will be described in greater detail hereinafter. As was the case when describing the anterior implant 10 of Fig. 1, the

imaginary boundaries of the various portions of the posterior implant 50 of Fig. 2 are indicated by dotted lines (i.e., in phantom) to facilitate consideration and discussion.

Returning now to Fig. 2, the tape portion 56, which is interposed between the lower portion 52 and the upper portion 54, has an imaginary central region 58 bounded by imaginary lines 60, 62, 64 and 66 and approximating the shape of a rectangle having a length of about 5 cm and a width of about .5 to 2 cm. The tape portion 56 also includes a pair of straps 68, 70 extending outwardly from opposite ends of the imaginary central region 58. The straps 68, 70, whose function will be described in greater detail hereinafter, typically have a width in a range of from about .5 cm to about 2 cm, a length of about 4 cm, if the straps 68, 70 are attached to and terminated at the sacrospinous ligaments, or about 20 cm, if the straps 68, 70 are passed through the pelvic floor via the buttocks with or without passing through the sacrospinous ligaments. While the straps 68, 70 preferably have a slight curvature as shown in Fig. 2, they could also extend in a linear fashion from opposite sides of posterior implant 50. Given the nature of the mesh material from which the posterior implant 50 is made, the width and length of the straps 68, 70 can be readily modified by the surgeon to meet the needs of a particular patient.

Still referring to Fig. 2, the lower portion 52, which has a generally triangular shape, depends downwardly from the tape portion 56. More particularly, the lower portion 52 is demarcated by a straight lower edge

72 having a length in a range of from about 1.5 cm to about 3.5 cm and a pair of downwardly converging side edges 74, 76 which are either straight or slightly concave. While the length of the side edges 74, 76 is typically in a range of from about 8 cm to about 12 cm, it should be appreciated by a person skilled in the art that the physical dimensions of the lower portion 52, including the length of the side edges 74, 76, are a function of the pelvic anatomy of the patient. More particularly, the size and shape of the lower portion 52 are specifically selected for the purpose of repairing a rectocele. A person skilled in the art will also appreciate that the shape and size of the lower portion 52 are subject to post-manufacture modification by the surgeon. In cases where a rectocele repair is not required but a vaginal vault suspension is, both the lower portion 52 and the upper portion 54 can be removed from the posterior implant 50, leaving the tape portion 56 to perform the vaginal vault suspension.

With continuing reference to Fig. 2, the upper portion 54, which is demarcated at its free end by an upper edge 78 and which otherwise approximates the shape of a rectangle having a length of from about 3 cm and a width of about 1 cm, extends upwardly from the tape portion 56. The primary purpose of the upper portion 54 is to provide a means for attaching the posterior implant 50 to the anterior implant 10. Thus, for a patient who does not need the anterior implant 10, it should be appreciated that the upper portion 54 of the posterior implant 50 can be removed by the surgeon before insertion of the posterior implant 50 in such patient. It should also be

appreciated that the surgeon can otherwise modify the size and shape of the upper portion 54 to meet his or her needs, such as when attaching the posterior implant 50 to the anterior implant 10. For instance, the upper edge 78 can be extended by as much as about 3 cm (as indicated in phantom in Fig. 2) to facilitate attachment of the posterior implant 50 to the anterior implant 10. Alternatively, such attachment can be facilitated by extending the lower edge 16 of the anterior implant 10 as described hereinabove.

Both the anterior implant 10 and the posterior implant 50 can be cut or punched out from a larger piece of the mesh fabrics mentioned hereinabove. If necessary, the loose ends of the severed filaments can be treated against unravelling by any suitable technique known in the art.

The anterior implant 10 and the posterior implant 50 may be provided in a variety of standard shapes and sizes (e.g., small, medium and large). After comparing these standard implants to the pelvic anatomy of a particular patient, the surgeon would select the one which best meets the patient's needs. If any modifications to the size and/or shape of the selected implant are required, they can be effected by the surgeon in the surgical arena.

The anterior implant 10 is used to make an anterior repair of a cystocele, while the posterior implant 50 is used to make a posterior repair of a rectocele. A vaginal vault suspension can be performed using the anterior implant 10 and/or the posterior implant 50. All of these treatments will be discussed in greater detail below.

I. Overview

A standard vaginal hysterectomy usually precedes any pelvic floor repair carried out in accordance with the present invention. Thus, as shown in Fig. 3, a vagina (V) is illustrated without its associated uterus.

Referring still to Fig. 3, a cystocele has been treated by an anterior repair performed with the anterior implant 10 of Fig. 1. Briefly, such a treatment involves the placement of the anterior implant 10 between the vagina (V) and the bladder (B).

Fig. 3 also illustrates how a rectocele has been treated by a posterior repair performed with the posterior implant 50 of Fig. 2. Briefly, such a treatment involves the placement of the anterior implant 50 between the vagina (V) and the rectum (R).

Since the uterus (not shown) has been removed from the vagina (V), an apical repair is also illustrated in Fig. 3. Briefly, such a repair involves using the anterior implant 10 and/or the posterior implant 50 to perform a vaginal vault suspension.

II. Anterior and Lateral Repair

A. Incision of the Anterior Vaginal Wall

The full thickness of the anterior vaginal wall is incised longitudinally to create an appropriately sized anterior vaginal incision. If respecting the bladder neck area and the apical part of the vagina, the anterior median colpotomy would start 3 cm from the vaginal vault and would stop at least 1cm from the bladder neck. If respecting the bladder neck area only, the

anterior median colpotomy would start at the vaginal vault and would stop at least 1cm from the bladder neck. Although not illustrated in the accompanying drawings, these procedures are well known to a person skilled in the art.

B. Bladder Dissection

This well known procedure, which is not illustrated in the accompanying drawings, involves a lateral dissection up to the vaginal cul-de-sac. The integrity of the endopelvic fascia is then checked.

In the absence of a defect, the dissection is carried out following the plane of the fascia until the inferior edge of the pubic ramus is reached. After inserting scissors between the levator ani and the bone, a finger is passed through the opening and then pushed until it comes into contact with the obturator membrane. Such a procedure is commonly referred to as a supra levator passage.

If, on the other hand, a lateral defect or a very weak fascia is found, the paravesical fossa is first opened with a finger. Since a complete dissection of the arcus tendinosus fascia pelvis is unnecessary, the finger feels the obturator foramen through the muscular pelvic side wall (levator ani and obturator muscles). Such a procedure is commonly referred to as a trans-levator passage.

C. Plication of the Pre-Vesical Fascia

This procedure is typically performed using a continuous suture of 2/0 absorbable monofilament suture. While not illustrated in the accompanying drawings, the procedure is well known to a person skilled in the art.

D. Trans-Obturator Passage

This procedure is illustrated in Figs. 4 and 5. The ideal zone for such a passage is the inferior and internal part of the obturator foramen, slightly above the ischio-pubic ramus (PR). It is located at the level of the arcus tendinosus internally and can be surgically defined by a bi-digital palpation.

Referring to Fig. 4, the surgeon would use a surgical knife (K), such as a scalpel, to make a 5mm skin incision (SI_1), facing the tip of the surgeon's index finger (IF) lateral to the labia majora. A conventional curved and eyed needle (N) adapted to carry a suture (S_1) is passed through the obturator foramen (OF) and then pushed around the ischio-pubic ramus (PR) until it comes into contact with the tip of the surgeon's index finger (IF).

With reference now to Fig. 5, the needle (N) is guided by the surgeon's index finger (IF) and pushed through the anterior vaginal incision (not shown) until it reaches the vaginal opening (VO). The surgeon can now hook the looped end of the suture (S_1) with his or her index finger, pulling it out of the patient through the vaginal opening (VO). After detaching the suture (S_1) from the needle (N) and withdrawing the needle (N) back through the skin

incision (SI_1), the suture (S_1) lies freely in the trans-obturator passage ready for attachment to the anterior implant 10 of Fig. 1 as will be described hereinafter.

The same procedure would then be performed on the opposite side of the patient using the same needle (N) or another identical needle. The result would be that there are now two sutures (S_1) and (S_2) extending from two skin incisions (SI_1) and (SI_2) to the vaginal opening (VO), where they are ready for attachment to the anterior implant 10 (see Fig. 6).

E. Anterior Implant Fixation

With particular reference to Fig. 6, the two sutures (S_1) and (S_2) are shown attached to the straps 42, 44, respectively, of the anterior implant 10. As illustrated in Fig. 6, both of the sutures (S_1) and (S_2) are pulled on in the direction of arrows AR_1 and AR_2, respectively, while the surgeon inserts the anterior implant 10 into the patient through the vaginal opening (VO) and then through the anterior vaginal incision (not shown). As the sutures (S_1) and (S_2) are continued to be withdrawn back through the skin incisions (SI_1) and (SI_2), respectively, the straps 42, 44 pass through their respective obturator membranes, finally emerging through the skin incisions (SI_1) and (SI_2), respectively. Each of the straps 42, 44 is given the correct tension so that the anterior implant 10 conforms as much as possible to the patient's surrounding tissues. The straps 42, 44 are then cut at skin level and abandoned without any additional fixation. The anterior implant 10 would now be laterally fixated between the bladder (B) and the vagina (V) as shown in Fig. 3. When the

endopelvic fascia is strong, the straps 42, 44 can be severed from the anterior implant 10, thereby avoiding the trans-obturator passage. In such a situation, the anterior implant 10 would be fixed laterally by two stitches on each of its sides.

Referring now to Fig. 7, as well as to Fig. 3, the anterior implant 10 is fixed bilaterally, in the vicinity of the corners 38, 40, to the anterior part of the pubo-coccygeous muscle (PM) close to its insertion by one stitch of braided absorbable size 0 suture, thereby achieving an anterior fixation of the implant. The anterior implant 10 is also fixed bilaterally, in the vicinity of the corners 24, 26, to the utero-sacral ligaments (US_1) and (US_2) a distance of 1 to 2 cm from the vaginal cuff (VC) by one stitch of braided absorbable size 0 suture. Alternatively, such posterior fixation of the anterior implant 10 can be achieved by attachment to the sacro-spinous ligaments (SS_1) and (SS_2) bilaterally or to the posterior implant 50, if a posterior repair is to be performed.

If no posterior repair is to be undertaken, an economical colpectomy, which would be limited to the edges of the vaginal incision, is performed as required. The anterior vaginal incision is then closed (as shown in Figs. 3 and 7) by a continuous absorbable size 0 suture up to the vaginal apex, making sure that the vaginal wall is not under tension.

With continuing reference to Figs. 3 and 7, a person skilled in the art will readily appreciate that the anterior implant 10 functions to repair lateral cystoceles, as well as a medial or central cystocele. It should also be

understood that the straps 42, 44 of the anterior implant 10 provide adequate lateral fixation so as to eliminate the need to stitch or staple the convex side edges 30, 32 to the arcus tendineous fascia pelvis (ATFP), thereby avoiding a very difficult and time-consuming stitching or stapling procedure.

III. Posterior Repair

A. Incision of the Perineum

This procedure, which is well known in the art and which is not depicted in the accompanying drawings, involves two basic steps. These steps are as follows: (1) the triangular incision of the perineal skin and excision; and (2) dissection of the perineal body.

B. Incision of the Posterior Vaginal Wall

The full thickness of the posterior vaginal wall is incised longitudinally from the perineal incision either up to 2cm from the vaginal apex or up to the vaginal apex, thereby creating an appropriately sized posterior vaginal incision. While this procedure is not illustrated in the accompanying drawings, it is well known in the art.

C. Rectal Dissection

The anterior and lateral wall of the rectum is bluntly dissected from the vagina. Since this procedure is well known to a person skilled in the art, it has not been depicted in the accompanying drawings.

D. Para-Rectal Space Dissection

Initially, the para-rectal space is entered bilaterally by gentle dissection. It is then dissected more deeply until the sacro-spinuous ligaments are exposed or simply palpated. Again, while this procedure is not illustrated in the accompanying drawings, it is well known in the art.

E. Plication of the Pre-Rectal Fascia

This procedure is typically performed using a continuous suture of 2/0 absorbable monofilament suture. Because this procedure is well known in the art, it too has not been depicted in the accompanying drawings.

F. Posterior Implant Fixation

With reference to Fig. 6, lateral fixation of the posterior implant 50 of Fig. 2 is achieved by inserting non-absorbable size 0 braided sutures (BS_1) and (BS_2) into the sacro-spinous ligaments (SS_1) and (SS_2), respectively, 2 to 3 cm medial to the sciatic spine on both sides of the patient's body. After attaching the straps 68, 70 of the posterior implant 50 to the braided sutures (BS_1) and (BS_2), respectively, the implant is inserted into the patient's body through the vaginal opening (VO) and then through the posterior vaginal incision (not shown). The braided sutures (BS_1) and (BS_2) are then used to attach their associated straps 68, 70 to the sacro-spinous ligaments (SS_1) and (SS_2), respectively, such that the posterior implant 50 is positioned between the vagina (V) and the rectum (R) as illustrated best in Fig. 8. It is also possible to attach the straps 68, 70 to the sacro-spinous ligaments (SS_1) and (SS_2) using glue, staples, tacks, anchors (e.g., MITEK's

"Fastin" threaded anchor or INFLUENCE's "Raz" soft-tissue anchoring system) or sewing devices such as United States Surgical Corporation's "Endostitch" mechanism.

Referring now to Fig. 8, as well as to Fig. 3, upper fixation of the posterior implant 50 is achieved by applying the upper portion 54 to the anterior wall of the high rectum without any fixation. Alternatively, and with reference to Fig. 3, the upper portion 54 of the posterior implant 50 can be fixed to the utero-sacral ligaments (US_1) and (US_2) by stitching or any other suitable means known in the art; or, if an anterior repair has been performed, it can be folded over the vaginal cuff (VC) and then attached to the lower portion 12 of the anterior implant 10 between the corners 24, 26 thereof.

With continuing reference to Figs. 3, 8 and 9, lower fixation of the posterior implant 50 is achieved by applying the lower portion 52 of the implant to the anterior wall of the mid and low rectum. The edges 74, 76 of the lower portion 52 are fixed to the pubo-rectal muscle by one or two stitches of absorbable braided 2/0 sutures (see Figs. 3 and 8). The lower edge 72 (i.e., the free end) of the lower portion 52 is attached to the perineal body (see Fig. 9) in order to treat or prevent associated descending perineum.

With the posterior implant 50 properly positioned between the vagina (V) and the rectum (R), the posterior repair is now complete. Closure of the posterior vaginal incision (not shown) is typically achieved by a continuous absorbable size 0 suture starting at the vaginal apex, making sure that the posterior vaginal wall is not under tension. A standard perineorraphy

is then performed covering the distal part of the posterior implant 50.

IV. Apical Repair

Apical fixation can be performed in accordance with three different techniques. Each of these techniques will be described below.

In accordance with one technique, the vaginal vault is fixed by the attachment between the utero-sacral ligaments and the anterior implant 10 and/or the posterior implant 50 (see Fig. 3). The suture is applied transversely, if the utero-sacral ligaments remain distinct, or longitudinally, if such ligaments have been brought together as per the McCall-type culdeplasty.

Another technique involves attaching the vaginal vault to the anterior implant 10 and/or the posterior implant 50 by trans-fixating absorbable 2/0 braided sutures. Like the preceding technique, this technique uses one or both of the implants 10, 50 to achieve the desired apical fixation.

The other apical fixation technique does not make direct use of either the anterior implant 10 or the posterior implant 50. More particularly, the vaginal vault is fixed independently of either of the implants 10, 50 by a standard bilateral sacro-spinous fixation.

* * *

What follows is a description of the two alternate embodiments referred to above and illustrated in Figs. 10 and 11. In describing these

alternate embodiments, elements which correspond to elements described above in connection with the embodiments of Figs. 1 and 2 will be designated by corresponding reference numerals increased by one hundred. Unless otherwise specified, the alternate embodiments of Figs. 10 and 11 are constructed and operate in the same manner as the embodiments of Figs. 1 and 2, respectively.

Referring to Fig. 10, there is shown an anterior implant 110 whose main difference in comparison to the anterior implant 10 of Fig. 1 involves the provision of two straps 142 on one side of the anterior implant 110 and two straps 144 on the opposite side of the anterior plant 110. Both of the straps 142 pass through the obturator foramen on one side of a patient, while both of the straps 144 pass through the obturator foramen on the other side of the patient's body. Each of the straps 142 exits the patient's body through a corresponding one of two small skin incisions at the perineum (i.e., groin) on one side of the body. Similarly, each of the straps 144 exits the patient's body through a corresponding one of two small skin incisions at the perineum (i.e., groin) on the other side of the body. As compared with the anterior implant 10, the anterior implant 110 provides increased lateral support in use as a result of the provision of the extra set of straps 142, 144, whose location allows the anterior implant 110 to be manufactured without the corners 34, 36 and 38, 40 which are characteristic of the anterior implant 10.

With reference to Fig. 11, there is shown a posterior implant 150 whose main difference in comparison to the posterior implant 50 of Fig. 2 involves the acute angle that straps 168, 170 form with the central longitudinal axis (L) of the anterior implant 150. The angle is specifically selected so as to reduce the amount of rectal constriction in the event that the posterior implant 150 shrinks when implanted in a patient's body.

It should be understood that the various embodiments described herein are merely exemplary and that a person skilled in the art may make many variations and modifications without departing from the spirit and scope of the invention as defined in the appended claims. For instance, if the uterus is conserved (i.e., no hysterectomy), the posterior fixation of the anterior implant 10 is done on the anterior part of the cervix, with the upper portion 54 of the posterior implant 50 being fixed on the posterior part of the cervix. Also, once the prolapse repair has been completed in accordance with the present invention, a vaginal incision can be made at the mid-urethral level and a sub-urethral sling inserted in accordance with a well known treatment for stress urinary incontinence. These and any and all additional variations and modifications are intended to be included within the scope of the invention as defined in the appended claims.

Claims

1. An implant (10;110) for treating central and lateral cystoceles present in a female patient, characterized by a body (12, 14; 112, 114) having a central longitudinal axis (L), an inboard area (A_1) through which said central longitudinal axis passes, said inboard area being sized and shaped so as to repair a central cystocele, at least one outboard area (A_2 and/or A_3) positioned on at least one side of said inboard area, said at least one outboard area being sized and shaped so as to repair a lateral cystocele, and stabilizing means (42, 44; 142, 144) for laterally stabilizing said body on both sides thereof independently of the patient's arcus tendineous fascia pelvis.

2. An implant (10; 110) according to Claim 1, characterized in that said stabilizing means includes at least one pair of straps (42, 44; 142, 144) extending laterally outward from opposite sides of said body, each of said straps being long enough to pass through a respective one of the patient's obturator foramens and out a corresponding skin incision formed in the patient's perineum proximal thereto.

3. An implant (10; 110) according to Claim 2, characterized in that said at least one pair of straps includes a first strap (42; 142) which extends laterally outward from one side of said body and a second strap (44;144) which extends laterally outward from the other side of said body.

4. An implant (10; 110) according to Claim 3, characterized in that said at least one outboard area includes a first outboard area (A_2) on

one side of said inboard area (A_1) and a second outboard area (A_3) on an opposite side of said inboard area (A_1).

5. An implant (10; 110) according to Claim 4, characterized in that said body includes a generally dome-shaped section (14; 114) having a first outer edge (30; 130) bordering at least a portion of said first outboard area (A_2) and a second outer edge (32; 132) bordering at least a portion of said second outboard area (A_3).

6. An implant (10; 110) according to Claim 5, characterized in that said first strap (42; 142) extends laterally outward from said first outer edge (30; 130) of said dome-shaped section (14; 114) and said second strap (44; 144) extends laterally outward from said second outer edge (32; 132) of said dome-shaped section (14; 114).

7. An implant (10; 110) according to Claim 6, characterized in that said first outer edge (30; 130) has a generally convex shape which substantially matches the shape of the arcus tendineous fascia pelvis on one side of the patient's body and said second outer edge (32; 132) has a generally convex shape which substantially matches the shape of the arcus tendineous fascia pelvis on the other side of the patient's body.

8. An implant (10; 110) according to Claim 7, characterized in that said body includes a generally funnel-shaped section (12; 112) having a wide portion which merges into said dome-shaped section (14; 114) at a wide end thereof and a narrow portion which extends away from said wide end of said dome-shaped section, said narrow portion being sized and shaped

so as to permit attachment of said funnel-shaped section (12; 112) to the patient's utero-sacral ligaments.

9. An implant (10; 110) according to Claim 8, characterized in that an end of said dome-shaped section opposite said wide end thereof includes a concave edge (28; 128) which merges into said first and second outer edges (30, 32; 130, 132) of said dome-shaped section (14; 114), said concave edge (28; 128) being sized and shaped so as to avoid contact with the patient's bladder neck while permitting attachment of said dome-shaped section (14; 114) to the patient's pubococcygeous muscle.

10. An implant (10) according to Claim 9, characterized in that said first strap (42) is positioned intermediate opposed ends (34, 38) of said first outer edge (30) of said dome-shaped section (14) and said second strap (44) is positioned intermediate opposed ends (36, 40) of said second outer edge (32) of said dome-shaped section (14).

11. An implant (110) according to Claim 9, characterized in that said at least one pair of straps includes a third strap (142) which extends laterally outward from said one side of said body along said first outer edge (130) of said dome-shaped section (114) and a fourth strap (144) which extends laterally outward from said other side of said body along said second outer edge (132) of said dome-shaped section (114).

12. An implant (110) according to Claim 11, characterized in that said first and second straps (142, 144) are located proximal to said concave edge (128) of said dome-shaped section (114) and said third and fourth straps (142, 144) are located proximal to said wide end of said dome-shaped section (114).

13. An implant (10; 110) according to Claim 2, characterized in that said body (12, 14; 112, 114) is made from a single sheet of a biocompatible mesh material, whereby said at least one pair of straps (42, 44; 142, 144) is formed monolithically with said body.

14. An implant (10; 110) according to Claim 1, characterized in that said body (12, 14; 112, 114) is formed monolithically with another implant (50; 150) adapted to treat a rectocele and/or a hysterocele.

15. An implant (50; 150) for treating a rectocele and a hysterocele present in a female patient, characterized by a body (52, 54; 152, 154) having a central longitudinal axis (L), a generally triangular-shaped section (52; 152) through which said central longitudinal axis (L) passes, said triangular-shaped section (52; 152) being sized and shaped so as to repair a rectocele and having a first edge (74; 174) extending along one side of said central longitudinal axis (L) and a second edge (76; 176) extending along an opposite side of said central longitudinal axis (L), a first strap (68; 168) attached to said first edge (74; 174) proximal to a wide end of said triangular-shaped section and extending laterally outward therefrom, and a second strap (70; 170) attached to said second edge (76; 176) proximal to said wide end

of said triangular-shaped section and extending laterally outward therefrom, said first and second straps (68, 70; 168, 170) cooperating with an intermediate portion (58; 158) of said body to form a generally arcuate tape-like segment sized and shaped so as to perform a vaginal vault suspension.

16. An implant (50) according to Claim 15, characterized in that said body (52, 54) includes attaching means (54; 154) for attaching said implant (50; 150) to another implant (10; 110) adapted to treat a cystocele.

17. An implant (50; 150) according to Claim 16, characterized in that said attaching means includes a generally rectangular-shaped section (54; 154) which merges into said triangular-shaped section (52; 152) at said wide end thereof, said rectangular-shaped section (54; 154) having a dimension, as measured along said central longitudinal axis (L) of said body, sufficient to permit said rectangular-shaped section (54; 154) to be folded over the patient's vaginal cuff.

18. An implant (50; 150) according to Claim 15, characterized in that said first and second straps (68, 70; 168, 170) are long enough for attachment to the patient's sacrospinous ligaments.

19. An implant (50; 150) according to Claim 15, characterized in that said first and second straps (68, 70; 168, 170) are long enough to extend through and beyond the patient's sacrospinous ligaments.

20. An implant (50; 150) according to Claim 15, characterized in that said body (52, 54; 152, 154) is made from a single sheet of a bio-compatible mesh material, whereby said first and second straps (68,

70; 168, 170) are formed monolithically with said triangular-shaped section (52; 152).

21. An implant (50; 150) according to Claim 15, characterized in that said body (52, 54; 152, 154) is formed monolithically with another implant (10; 110) adapted to treat a cystocele.

22. An implant (150) according to Claim 15, characterized in that said first and second straps (168, 170) extend toward and beyond said wide end of said triangular-shaped section (152) forming an acute angle with said central longitudinal axis (L).

23. A procedure for treating a cystocele present in a female patient characterized by the steps of: making a first skin incision in the patient's perineum proximal to one of the obturator foramens; making a second skin incision in the patient's perineum proximal to the other obturator foramen; providing an anterior implant (10; 110) with at least a pair of laterally extending straps (42, 44; 142, 144); inserting said anterior implant (10;110) into the patient's pelvic area through the patient's vaginal opening and an anterior incision in the vaginal wall; passing one of said straps (42; 142) through said one obturator foramen and out said first skin incision; passing another of said straps (44; 144) through said other obturator foramen and out said second skin incision; and pulling on said one strap (42; 142) and said another strap (44; 144) until said anterior implant (10; 110) is properly positioned between the patient's bladder and vagina to repair the cystocele.

24. A procedure according to Claim 23, further chracterized by the step of attaching said anterior implant (10; 110) to a posterior implant (50; 150) adapted to treat a rectocele and/or a hysterocele.

25. A procedure according to Claim 24, characterized in that said anterior (10; 110) and posterior (50; 150) implants are attached to each other after their introduction into the patient's body.

26. A procedure according to Claim 24, characterized in that said anterior (10; 110) and posterior (50; 150) implants are attached to each other prior to their introduction into the patient's body.

27. A procedure for treating a rectocele and a hysterocele present in a female patient, characterized by the steps of: providing a posterior implant (50; 150) with a pair of laterally extending straps (68, 70; 168, 170); inserting said posterior implant (50; 150) into the patient's pelvic area through the patient's vaginal opening and a posterior incision in the vaginal wall; placing said posterior implant (50; 150) between the patient's rectum and vagina to repair the rectocele; attaching one of said straps (68; 168) to one of the patient's sacrospinous ligaments; and attaching the other of said straps (70; 170) to the patient's other sacrospinous ligament, thereby repairing the patient's hysterocele.

28. A procedure according to Claim 27, further characterized by the step of attaching said posterior implant (50; 150) to an anterior implant (10; 110) adapted to repair a cystocele.

29. A procedure according to Claim 28, characterized in that said anterior (10; 110) and posterior (50; 150) implants are attached to each other after their introduction into the patient's body.

30. A procedure according to Claim 28, characterized in that said anterior (10; 110) and posterior (50; 150) implants are attached to each other prior to their introduction into the patient's body.

31. A procedure according to Claim 27, characterized in that said one strap (68; 168) extends through and beyond its associated sacrospinous ligament and said other strap (70; 170) extends through and beyond its associated sacrospinous ligament.

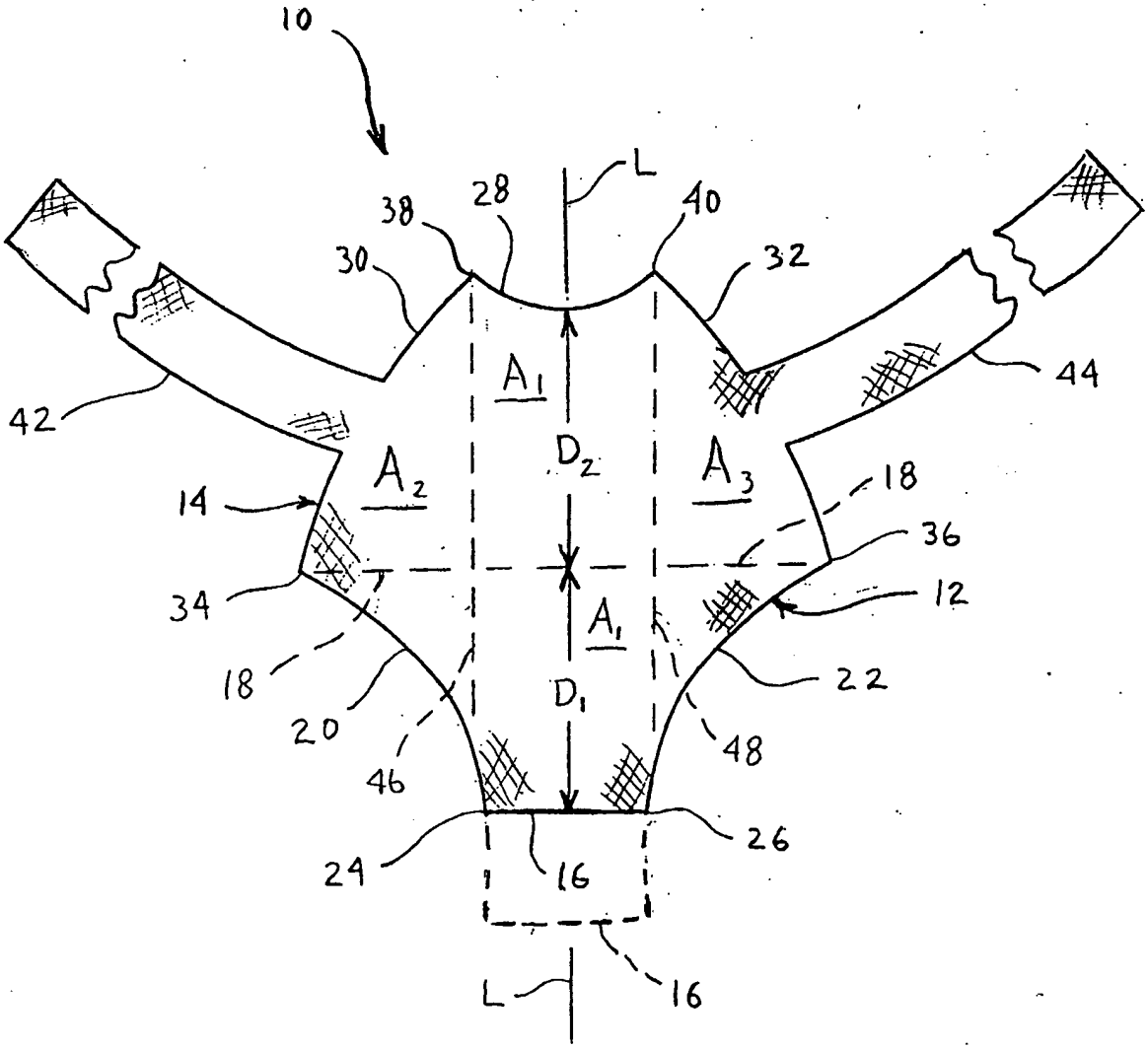

10
L
38
28
40
30
32
A1
42
44
A2
D2
A3
14
18
36
34
12
A1
18
22
D1
20
48
46
26
24
16
L
16

FIG. 1

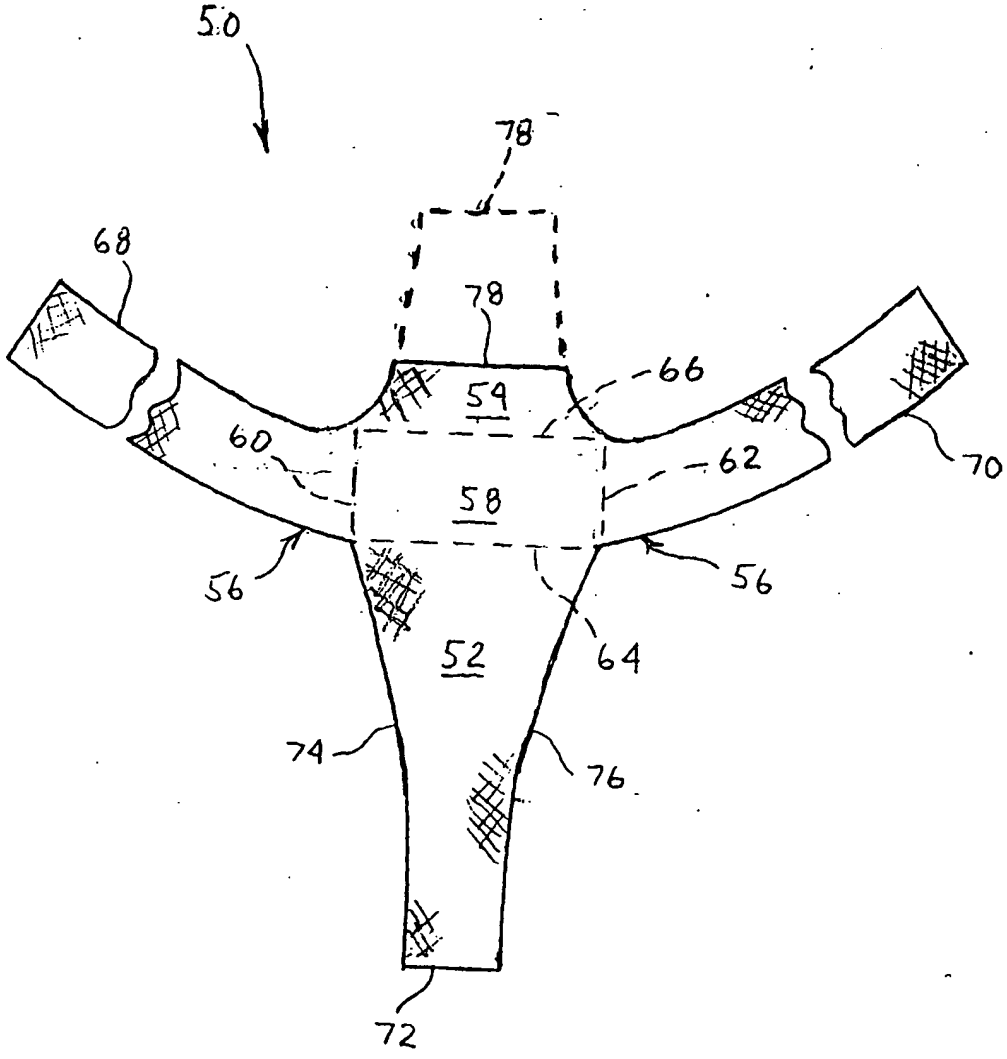


FIG. 2

FIG. 3

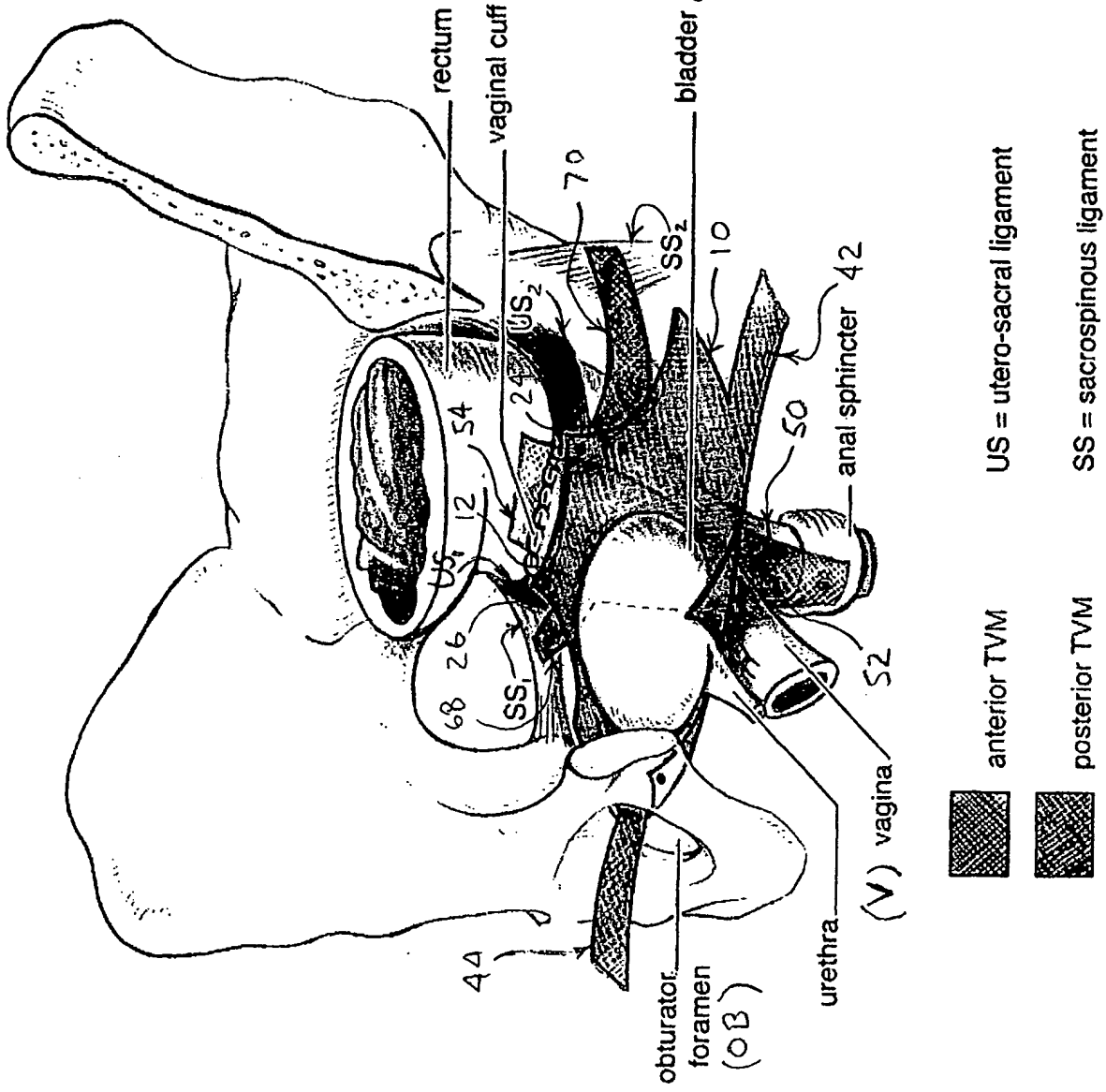

rectum (R)
vaginal cuff (VC)
bladder (B)
70
SS_2
10
42
anal sphincter
50
54
24
US_2
12
US_1
26
68
SS_1
52
(V) vagina
urethra
obturator foramen (OB)
44
US = utero-sacral ligament
SS = sacrospinous ligament
anterior TVM
posterior TVM

FIG. 4

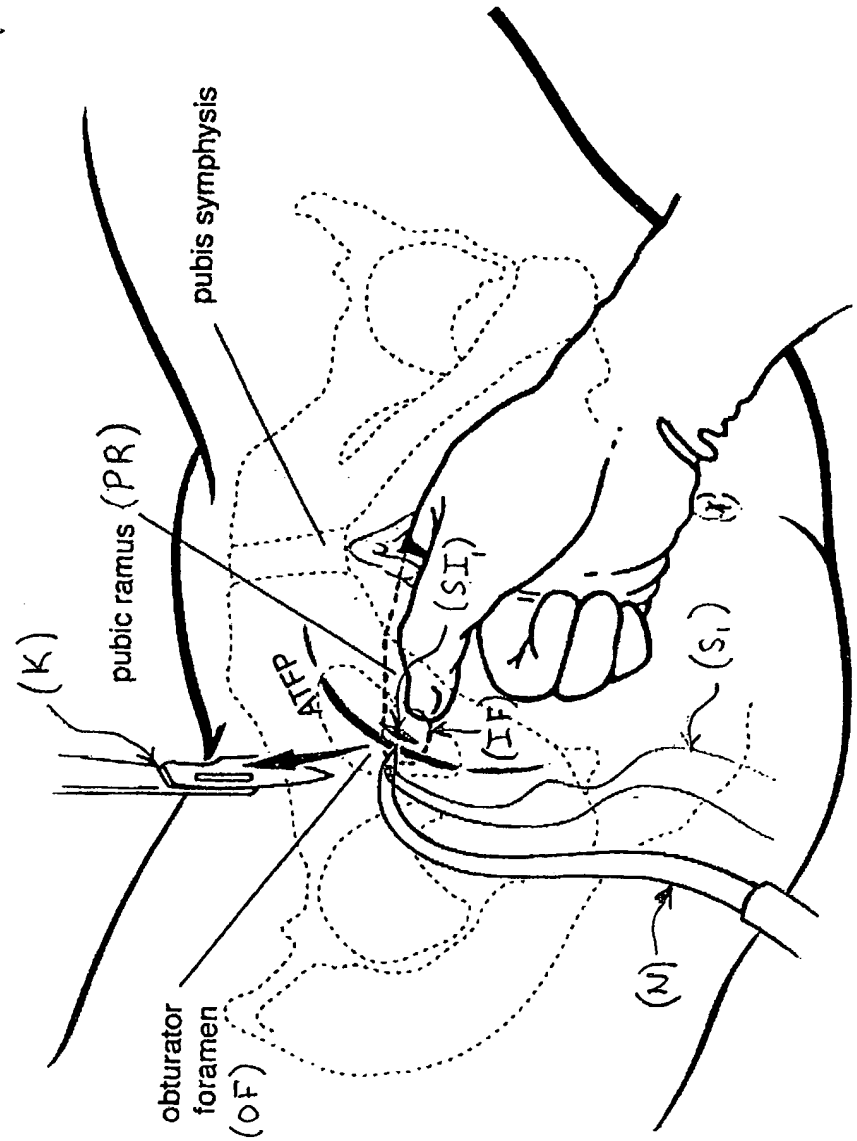
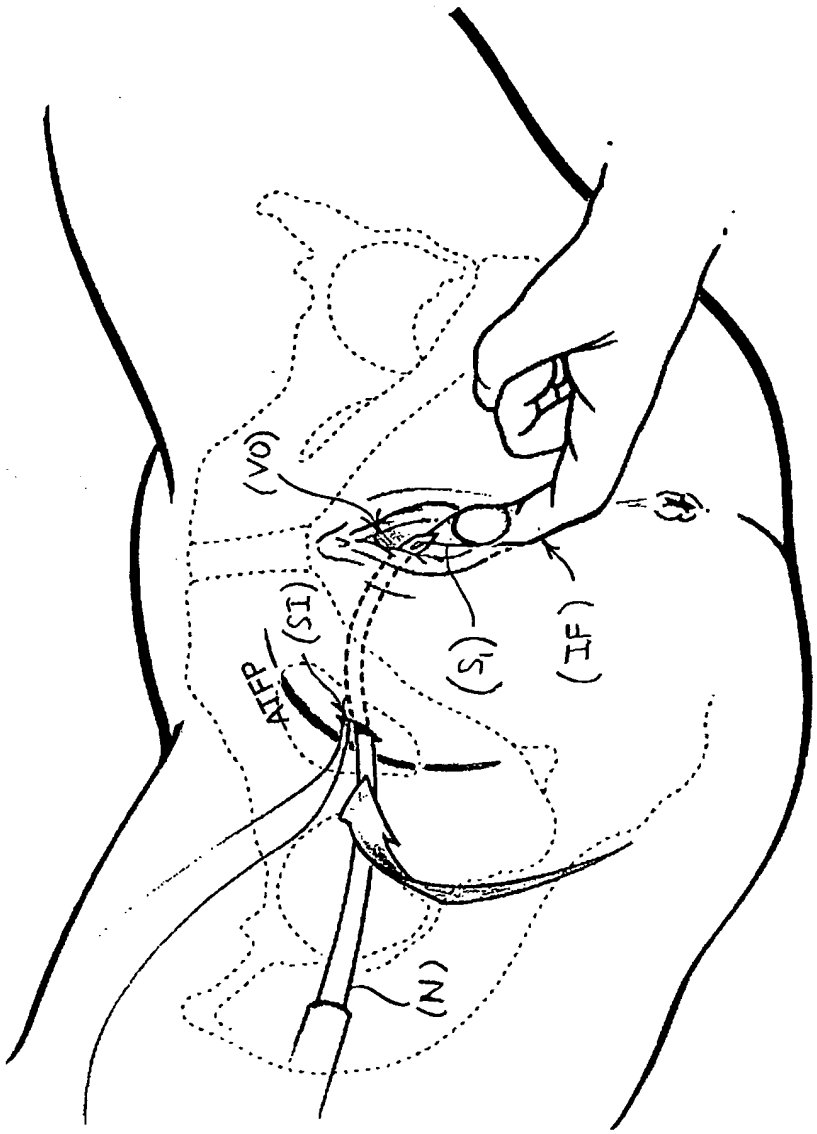
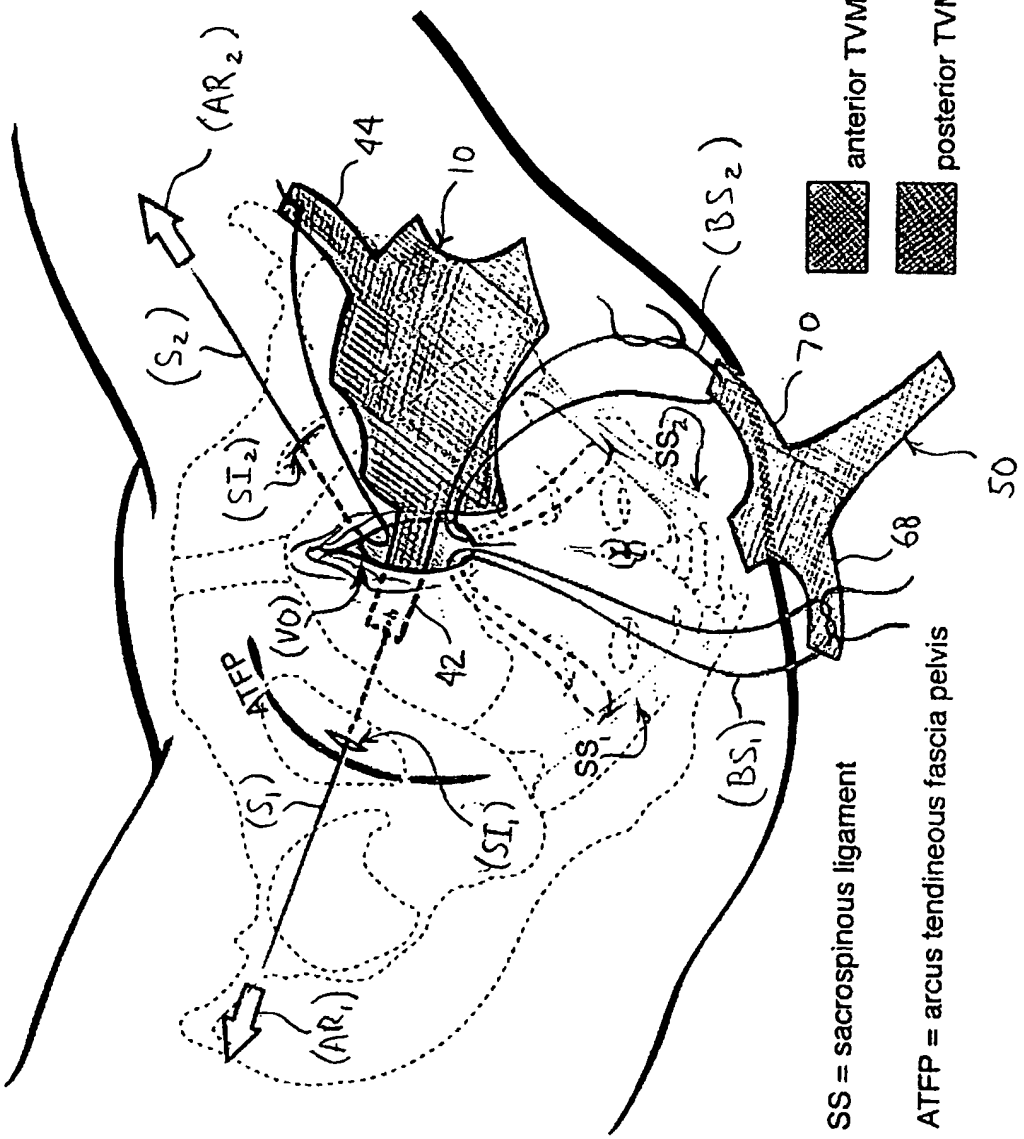

pubis symphysis
pubic ramus (PR)
(K)
ATFP
(SI)
(IF)
(S1)
(U)
obturator foramen (OF)
(N)
ATFP = arcus tendineous fascia pelvis

FIG.5



ATFP = arcus tendineous fascia pelvis

FIG. 6


(AR2)
(S2)
(SI2)
44
10
(BS2)
anterior TVM
posterior TVM
70
SS2
50
68
(VO)
42
ATFP
(S1)
(SI1)
SS
(BS1)
(AR1)
SS = sacrospinous ligament
ATFP = arcus tendineous fascia pelvis

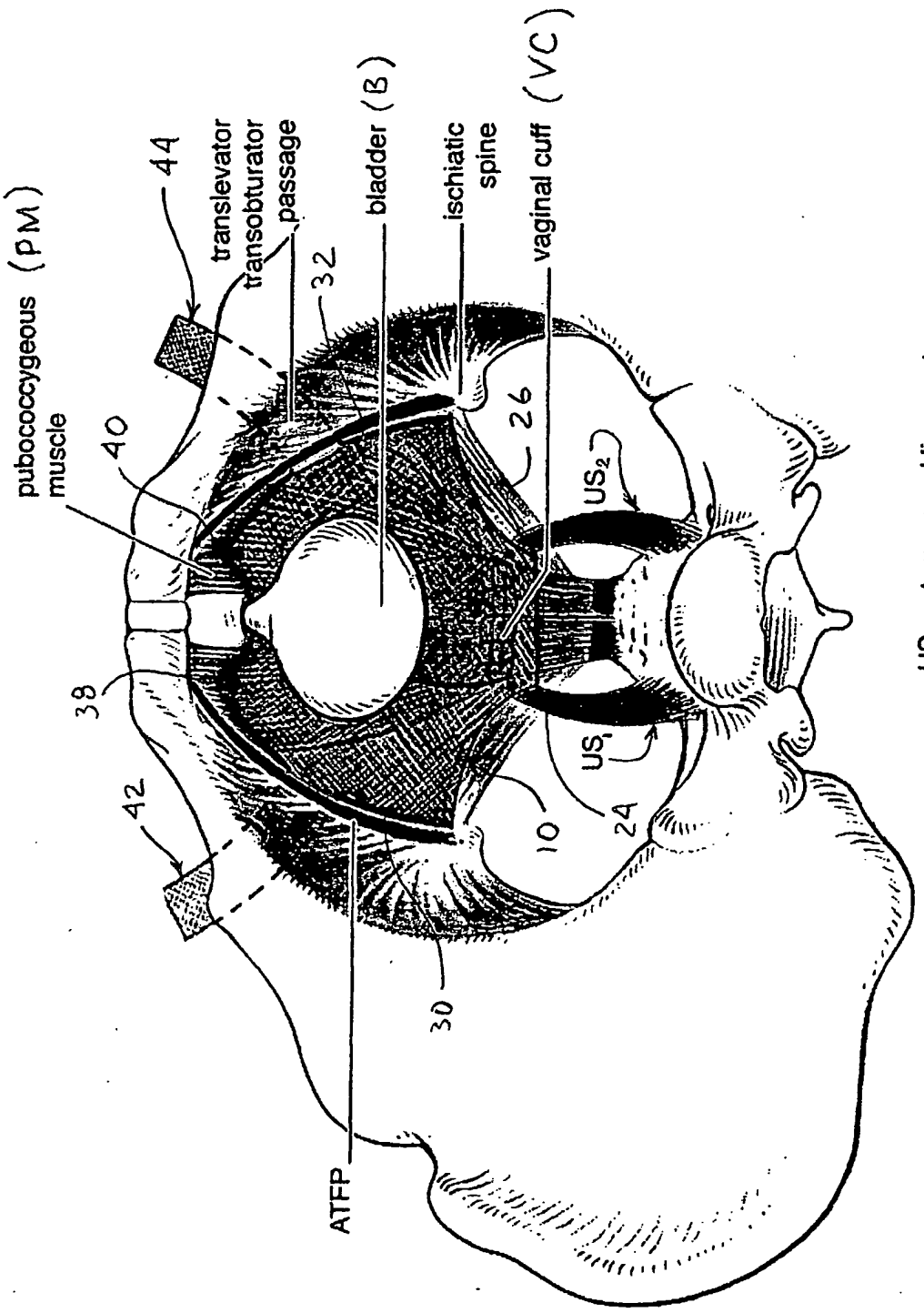
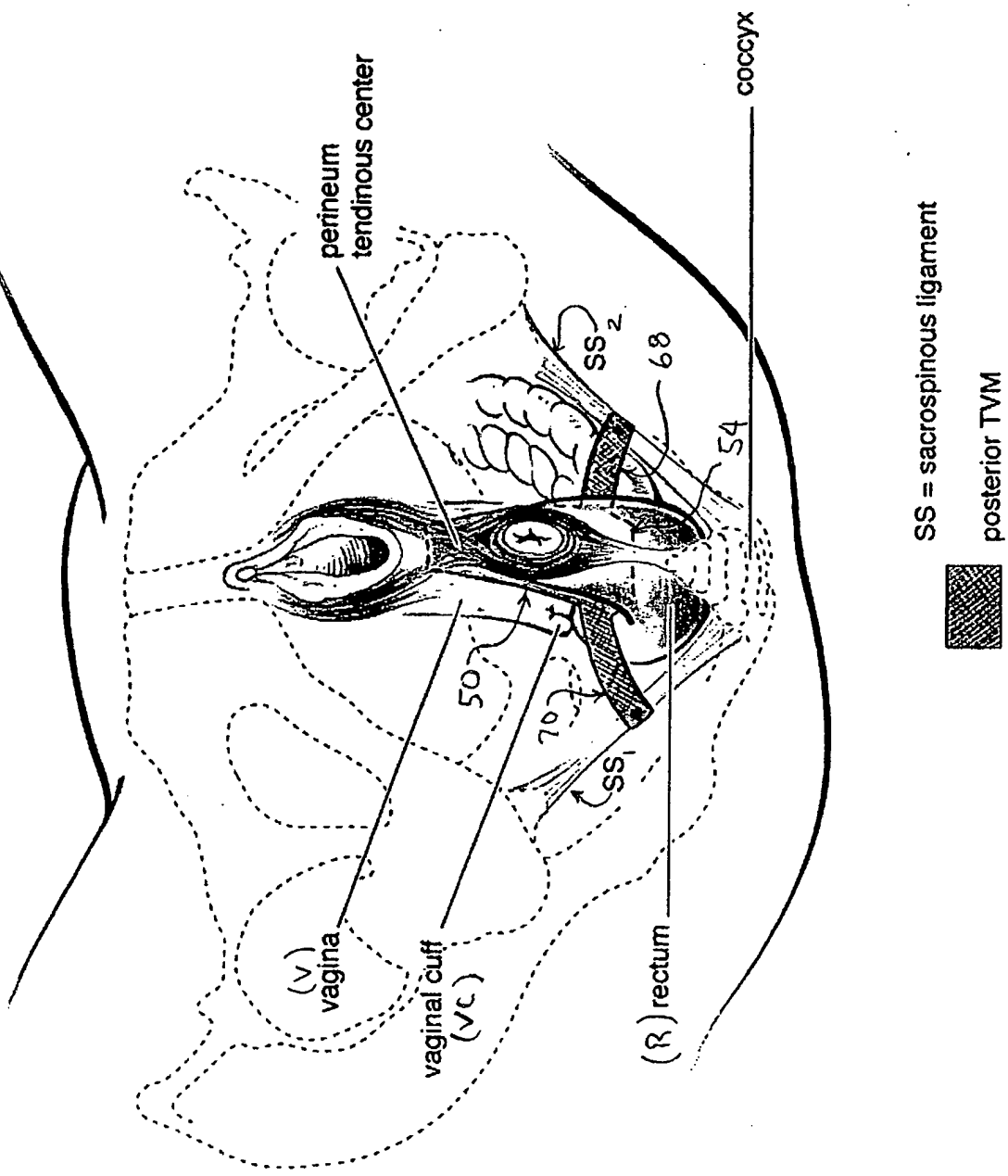

pubococcygeous (PM) muscle
44
translevator
transobturator passage
32
bladder (B)
ischiatic spine
vaginal cuff (VC)
40
26
US2
38
US1
42
10
24
30
ATFP
US = utero-sacral ligament
ATFP = arcus tendineous fascia pelvis
anterior TVM

FIG. 7

FIG. 8


perineum
tendinous center
coccyx
SS2
68
54
50
70
SS1
(V) vagina
vaginal cuff (VC)
(R) rectum
SS = sacrospinous ligament
posterior TVM

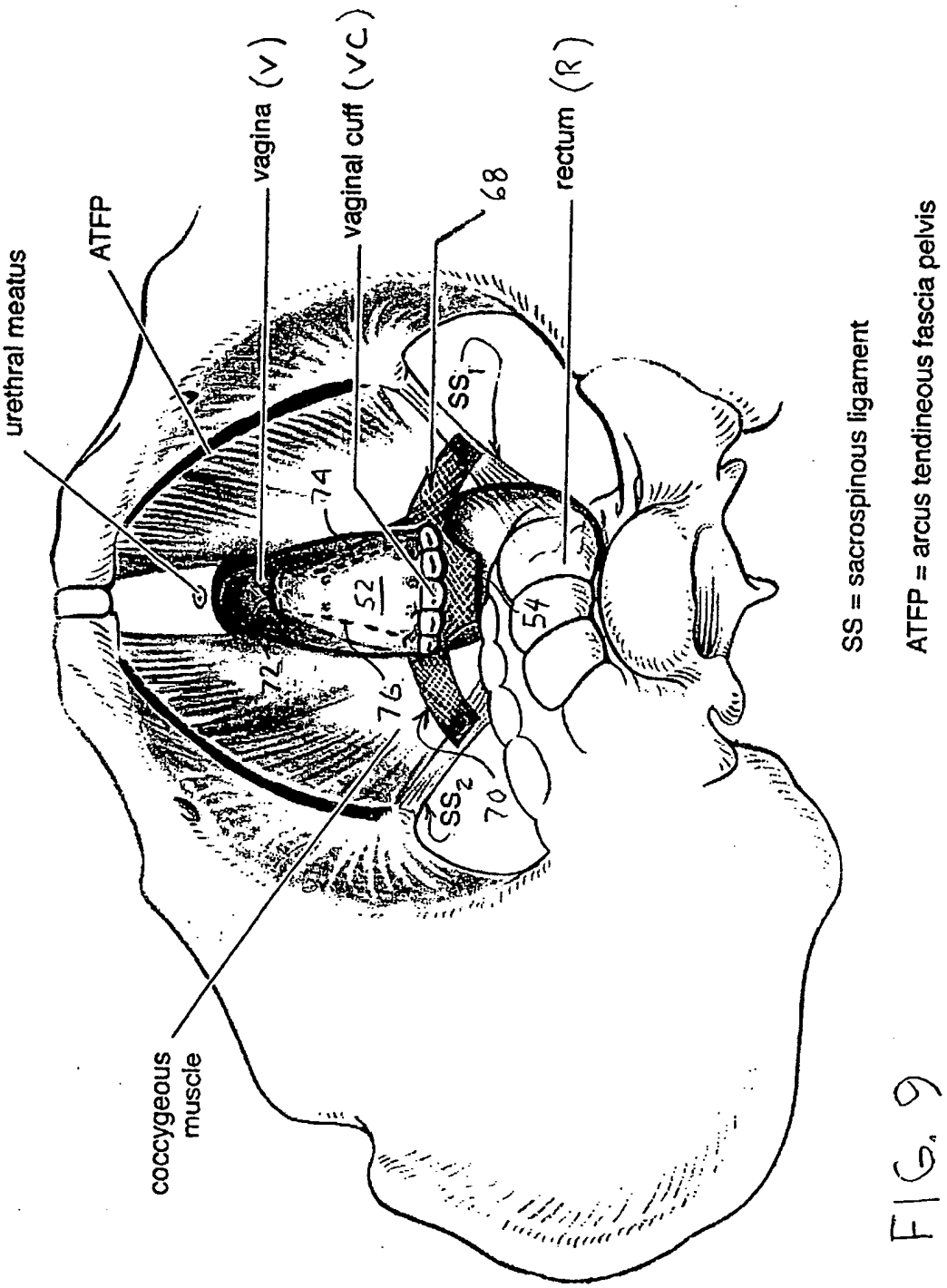

urethral meatus
ATFP
vagina (V)
vaginal cuff (VC)
rectum (R)
68
74
52
72
76
70
54
SS1
SS2
coccygeous muscle
SS = sacrospinous ligament
ATFP = arcus tendineous fascia pelvis
posterior TVM

FIG. 9

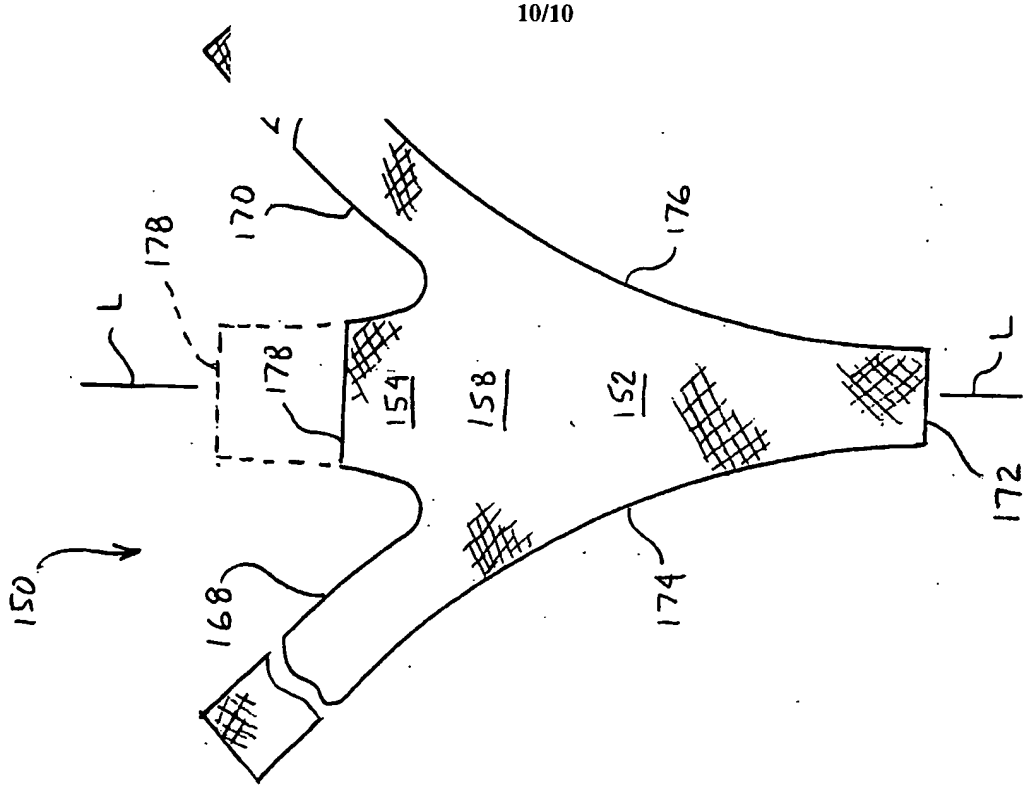

150
168
170
178
178
L
154
158
152
176
172
174
L

FIG. 11

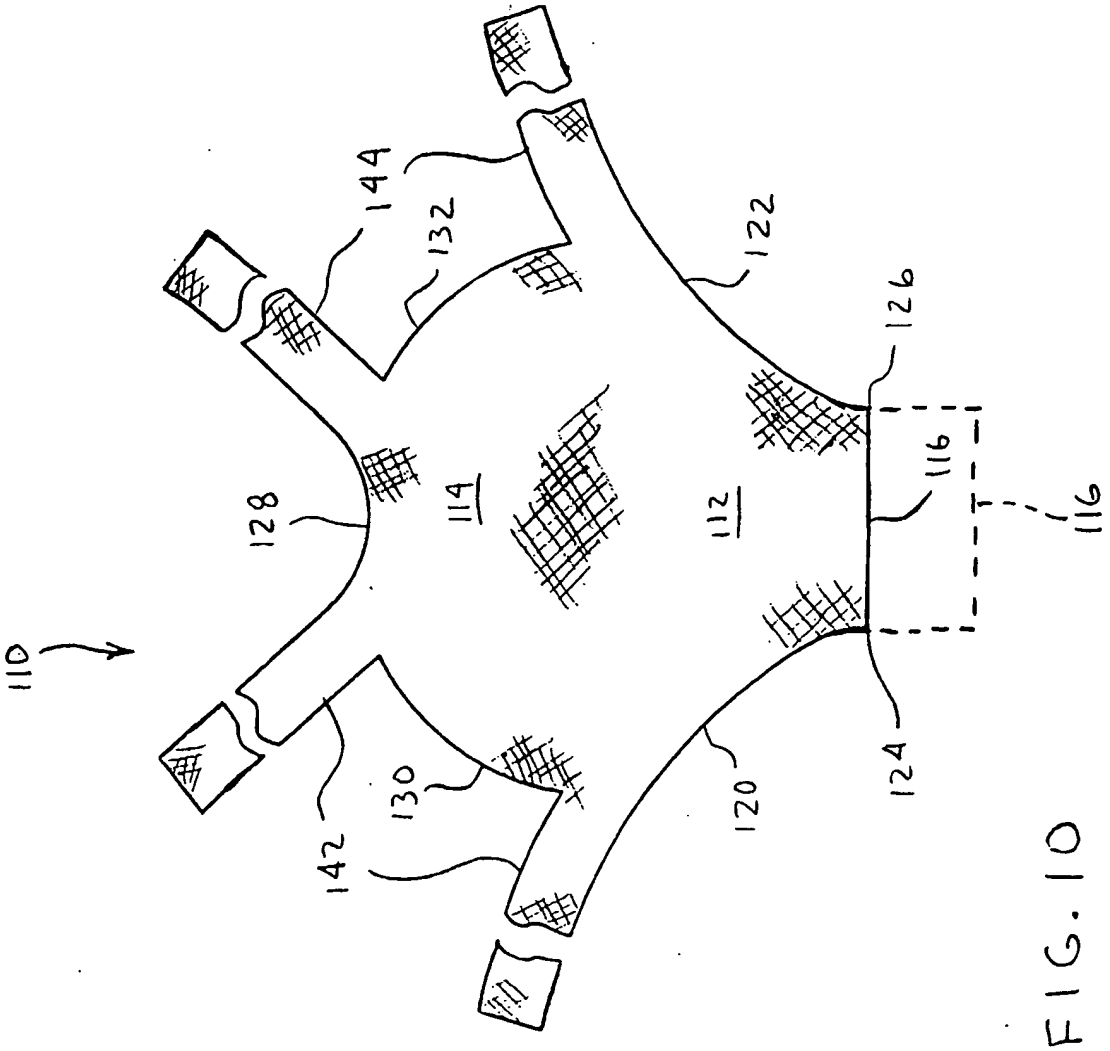

110
142
130
144
132
128
114
112
122
126
116
116
124
120

FIG. 10

INTERNATIONAL SEARCH REPORT

Internati pplication No
PCT/IB 03/01231

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 02 38079 A (ETHICON GMBH ;MIGLIARI ROBERTO (IT)) 16 May 2002 (2002-05-16) cited in the application page 3, line 14 -page 6, line 2 page 8, line 25 -page 9, line 18; figure 1	1-7
A	---	13-16, 18-21
A	US 6 042 534 A (GELLMAN BARRY N ET AL) 28 March 2000 (2000-03-28) column 1, line 10 -column 1, line 14; claims 1,7-9; figures 1,2B,3A,8B	1-4,8, 11, 13-17, 20,21
A	--- US 6 010 447 A (KARDJIAN PAUL M) 4 January 2000 (2000-01-04) -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 August 2003	18/08/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Merté, B

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter al application No.
PCT/IB 03/01231

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23-31
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery; in particular, the method comprises the invasive steps of making various incisions and inserting the device into the body of a patient.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Internati pplication No
PCT/IB 03/01231

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0238079 A	16-05-2002	DE 10056169 A1	06-06-2002
		AU 2952502 A	21-05-2002
		CA 2428652 A1	16-05-2002
		WO 0238079 A2	16-05-2002
US 6042534 A	28-03-2000	AU 6329598 A	08-09-1998
		DE 69808614 D1	14-11-2002
		DE 69808614 T2	18-06-2003
		EP 0983033 A1	08-03-2000
		JP 2001511685 T	14-08-2001
		WO 9835632 A1	20-08-1998
US 6010447 A	04-01-2000	NONE	